IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JUDITH PUSEY, et al.	:	CIVIL ACTION
	:	
v.	:	
	:	
BECTON DICKINSON AND CO.	:	NO. 10-3344

MEMORANDUM

Dalzell, J. June 7, 2011

Plaintiffs Judith ("Judith") and Donald Pusey ("Donald") sue defendant Becton, Dickinson and Co. ("Becton") in this product liability action.[1] Plaintiffs' claims arise out of a left breast expansion procedure performed upon Judith using a syringe Becton manufactured. Following this procedure, Judith's breast became infected, necessitating the removal of her left breast expander. At around the same time, Becton recalled all 60 mL syringes produced between 2005 and 2007, as well as some produced in 2008, due to packaging issues. This recall included the syringe used in Judith's procedure.

Specifically, plaintiffs assert five claims against Becton: (1) negligence, (2) strict liability under § 402A of the Restatement (Second) of Torts, (3) breach of express and implied warranty of merchantability, (4) breach of express and implied

[1] By stipulation, the parties dismissed defendants Baxter International, Inc. and Baxter Healthcare Corp. on January 10, 2011.

warranty of fitness for a particular purpose, and (5) loss of consortium (on Donald's behalf only).[2] Becton filed a motion for summary judgment, to which the plaintiffs responded. Becton then replied. For the reasons set forth below, we will grant Becton's motion and dismiss plaintiffs' claims.

I. Factual Background

Under Fed. R. Civ. P. 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law," where "[a] party asserting that there is a genuine dispute as to a material fact must support that assertion with specific citations to the record." Bello v. Romeo, 2011 WL 1519389, at *3 (3d Cir. 2011) (citing Rule 56(c)). Ordinarily, we would begin by reciting the undisputed facts in this matter, and would then consider the disputed facts that the parties have supported with specific citations to the record. This case, however, presents a somewhat unusual scenario:

[2] In Count VI of their complaint, the Puseys assert a claim for punitive damages. Pl.'s Compl. ¶¶ 62-67. Since this constitutes a demand for relief, not an assertion of liability, we will not treat it as a separate claim.

plaintiffs seek to avoid being bound by their citations to defendant's exhibits.

The plaintiffs preface their response to Becton's facts with the caveat that "[i]n responding to defendant's allegations, plaintiff has merely reviewed defendant's documentation. Plaintiff's [sic][3] responses are predicated upon defendant's own documentation. Plaintiff's responses are not an admission that defendant's documentation is correct." Pls.' Resp. to Def.'s Facts in Supp. of Mot. Summ. J. ("Pls.' Resp. to Facts") at 1. This disclaimer is consistent with plaintiffs' argument that "defendant seeks summary judgment without affording plaintiff any discovery or the opportunity of engaging in any discovery," and their assertion that Becton has declined to respond to deposition notices or interrogatories that they served in July and September of 2010, respectively. Pls.' Mem. in Supp. of Resp. to Def.'s Mot. Summ. J. ("Pls.' Resp.") at 5-6. Plaintiffs thus claim that Becton's motion for summary judgment is premature, presumably in an attempt to (1) excuse any failure on their part to support

[3] Throughout plaintiffs' briefing, their possessives relating to themselves refer to "plaintiffs'" and "plaintiff's"; they did the same when not using possessives. For precision's sake, we will hereafter quote these references as their counsel used them, and dispense with further use of "[sic]".

factual assertions with citations to the record, and (2) qualify any citations on their part to Becton's exhibits.

It is true that we issued an order in a related case, Civil Action No. 10-348,[4] "authorizing defendant to get a copy of Judith Pusey's medical records" and instructing Becton to "DELIVER to plaintiffs' counsel all documents related to the decision to recall the product at issue in this case," Mar. 10, 2010 Order, ¶¶ 1-2 (docket entry # 7), and that we have not since broadened the scope of discovery in this case. Plaintiffs have also attached letters to their response to defendant's motion for summary judgment that document Becton's July 12, 2010 refusal to provide dates for depositions and its September 27, 2010 confirmation that it would not respond to plaintiffs' interrogatories until after the deposition of Judith's doctor, R. Barrett Noone. Exs. A and C to Pls.' Resp.

As Becton points out, however, plaintiffs have not identified any hitherto unavailable avenues of discovery that might produce information relevant to the disputed issues in this

[4] The Puseys originally brought Civil Action No. 10-348 against Becton alone and later filed the present action against Becton, Baxter International, Inc., and Baxter Healthcare Corp. We consolidated the two actions on July 9, 2010 and instructed the Clerk to close Civil Action No. 10-348 statistically.

matter. Def.'s Reply in Supp. of Mot. Summ. J. ("Def.'s Reply") at 6. Thus, the parties have available to them all of Becton's documentation regarding its recall of the 60-mL syringes,[5] as well as all of Judith's medical records and the deposition testimony of the physician who performed Judith's procedure. It is by no means clear that deposing Becton's representatives or propounding interrogatories upon them would add to these materials and, more to the point, plaintiffs certainly have not explained how it might. Moreover, though counsel for the parties have met at length with the Court three times since the issuance of our March 10, 2010 Order, plaintiffs' counsel has not once expressed to us any need for expanded discovery.[6]

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[5] The Puseys note that "many of the pages of defendant's report have been partially deleted and/or blackened out in their entirety -- pp. 89-100. Furthermore, the defendant has objected to, and has not produced, documentation requested by plaintiff. . . " Pls.' Resp. at 13. Plaintiffs filed a motion to compel discovery on August 24, 2010 seeking the "production of legible unredacted documents," Pls.' Mot. Compel at 1, and after reviewing the unredacted documents in camera we granted this motion in part. Nov. 3, 2010 Order. Plaintiffs filed no further motions to compel. We will thus not entertain claims that plaintiffs have been denied any "documents related to the decision to recall the product at issue in this case" that we in fact ordered Becton to produce in our March 10, 2010 Order.

[6] It bears noting that these conferences were neither brief nor in any way pro forma. To the contrary, they were protracted and highly substantive.

In particular, plaintiffs' counsel voiced no objection when we, at a January 3, 2011 conference, proposed that Becton file any motion for summary judgment by January 18, 2011. All relevant discovery in this matter has thus been completed and plaintiffs long ago waived any objections they might have had regarding the ripeness of this matter for summary judgment. We consequently reject any attempt on plaintiffs' part to rely "upon defendant's own documentation" in responding to Becton's motion for summary judgment without "admi[tting] that defendant's documentation is correct." Pls.' Resp. to Facts at 1. The record is complete. We will not credit any of plaintiffs' assertions as to supposed genuine disputes of material fact unless they are supported, as Rule 56(c) requires, with specific citations to the record, and we will take as undisputed any facts that are not contested in the record.

Having resolved this issue, we proceed to a recitation of the undisputed facts. In February of 2008, after a mastectomy following a diagnosis of breast cancer, Judith came under the care of R. Barrett Noone, M.D. for reconstruction of her left breast. Def.'s Facts in Supp. of Mot. Summ. J. ("Def.'s Facts") ¶¶ 3, 73; Pls.' Resp. to Facts ¶¶ 3, 73. Over the course of a series of office visits between February and July of 2008, Dr.

Noone used a saline solution to inflate a temporary tissue expander implanted in Judith's chest, making the final scheduled inflation on July 11, 2008. Def.' Facts ¶¶ 4-5, 76; Pls.' Resp. to Facts ¶¶ 4-5, 76. Dr. Noone used a variety of medical products to perform the inflations, including saline solution manufactured by Baxter International, Inc. and Baxter Healthcare Corporation; a winged infusion set manufactured by B/Braun Medical, Inc.[7]; a 60 mL syringe manufactured by Becton; a 16-gauge needle to withdraw the saline; an anesthetic product; and a 9-inch needle to inject the anesthetic. Def.'s Facts ¶¶ 77-79; Pls.' Resp. to Facts ¶¶ 77-79.

After developing swelling and redness in her chest, Judith saw Dr. Noone on July 17, 2008, and the next day Dr. Noone came to the belief that Judith had an infection. Def.'s Facts ¶¶ 80-81; Pls.' Resp. to Facts ¶¶ 80-81. According to the complaint, Judith developed this infection in her chest within forty-eight hours after her final scheduled inflation on July 11, 2008, Def.'s Facts ¶ 5; Pls.' Resp. to Facts ¶ 5. Dr. Noone's deposition testimony corroborates this claim. Dep. of Dr. Noone, Ex. 11 to Def.'s MSJ ("Dep. of Dr. Noone"), at 177. On July 20,

[7] B/Braun Medical, Inc. has never been a party to this case.

2008, Dr. Noone drained an abscess on Judith's chest and removed the tissue expander, which had indeed become infected. Tests upon fluid aspirated from Judith's chest revealed the presence of a bacterial infection known as coagulase negative staphylococcus, "a Gram-positive organism which is commonly on the skin" and is "the most common cause of implant infections." Def.'s Facts ¶¶ 82-84 (quoting Dep. of Dr. Noone at 155); Pls.' Resp. to Facts ¶¶ 82-84.

Between July 15 and July 23, 2008, Dr. Noone received a notice of recall from Becton, Def.'s Facts ¶ 85; Pls.' Resp. to Facts ¶ 85, dated July 15, 2008. Def.'s Facts ¶ 51 (citing Ex. 2). Becton's notice concerned its 60-mL Luer-Lok Syringes. The notice explained that "unit package seal integrity (and resulting product sterility) can be adversely affected when the product is exposed to low atmospheric pressure experienced at high altitudes (e.g. during product shipping)," and urged all distributors and customers to return syringes from lots beginning with 5, 6, or 7, as well as some lots beginning with 8. Def.'s Facts ¶¶ 21, 52,

55-56 (quoting Ex. 2[8]); Pls.' Resp. to Facts ¶¶ 21, 52, 55-56. The notice stated that:

> In order to make the recall practical for customers to implement, BD has requested the return of lots beginning with the numbers 5, 6, or 7. While not all lots beginning with the digits 5, 6 and 7 exhibit the issue, it is much easier to instruct customers to return these lots, rather than have customers examine/check a more comprehensive list of affected and unaffected lots.

Def.'s Facts ¶ 58 (quoting Ex. 2); Pls.' Resp. to Facts ¶ 58.

Upon receiving Becton's recall notice, Dr. Noone instructed his staff to check their supply of 60 mL syringes to determine whether any fell within the lot numbers identified in the notice. Dr. Noone's staff identified one box of syringes that matched a lot number mentioned in the notice, and found that a 60 mL syringe from this box had been used to treat Judith. Def.'s Facts ¶¶ 86-88; Pls.' Resp. to Facts ¶¶ 86-88. Dr. Noone's office returned the remaining syringes in the box to Becton. Def.'s Facts ¶ 89; Pls.' Resp. to Facts ¶ 89. Dr. Noone did not observe any package seal failure in any 60 mL syringe used to treat Judith, and Dr. Noone did not believe that any

[8] Because the only exhibits we will consider in ruling on defendant's motion for summary judgment are those attached to that motion, we will hereafter simply cite those exhibits by number without specifying that they are "to Def.'s MSJ."

member of his staff checked any of the syringes in the recalled box to see if any of the seals were open. Def.'s Facts ¶¶ 104-05; Pls.' Resp. to Facts ¶¶ 104-05.

Until Dr. Noone received Becton's recall notice, he had no opinion as to what might have caused Judith's infection. Def.'s Facts ¶ 95. After receiving the notice, Dr. Noone determined that "this could be a cause of the infection because of the timing of the use of that syringe," id. at 96 (quoting Dep. of Dr. Noone, Ex. 11 at 190), and discussed this possibility with Judith. Id. at 97. Dr. Noone admitted, however, that his only source of information about the recall was the recall notice itself, Def.'s Facts ¶ 90; Pls.' Resp. to Facts ¶ 90, and agreed that "the only reason that [he] believe[d] that the syringe is the more likely source of the infection than the other products [is] because of the recall notice that [he] received." Def.'s Facts ¶ 107 (quoting Dep. of Dr. Noone at 192). Dr. Noone offered only a qualified opinion, moreover, that the syringe was the source of Judith's infection, with "other potential sources" such as "needle used, saline inflation." Id. ¶¶ 98-100 (quoting Dep. of Dr. Noone at 191-92).

Becton's recall of the 60 mL syringes resulted from the discovery in 2007 of products with open seals and the internal

investigation that followed.[9] Becton manufactured its 60 mL syringes in Columbus, Nebraska. Def.'s Facts ¶ 22.[10] In June of 2007, Becton discovered that six lots of 60 mL Luer Lok syringes at its distribution center in Cuautitlan, Mexico contained product with open seals. Def.'s Facts ¶ 26; Pls.' Resp. to Facts ¶ 26. Failure rates among the defective lots discovered in

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[9] The parties offer differing characterizations of the seal failures and Becton's resulting investigations -- neither of which are fully corroborated by the record. The defendant, in particular, offers an array of details unsupported by the record citations offered. To cite but a few examples, Becton asserts that "[p]er BD's Quality Control acceptance criteria, a 0.25% AQL (using American National Standard Z1.4) is used when determining acceptance criteria for open seals," Def.'s Facts ¶ 28, citing to Ex. 3 at BD000044 -- which contains no mention of "American National Standards." Becton claims that "[s]ubsequent testing and analysis did not demonstrate any package seal issues with 60 ML syringes manufactured on the 860 Line 1 production line," id. ¶ 32, citing to Ex. 4 at BD000060 -- but the cited materials state a much more limited proposition, that "[t]he product packaged on Line 1, having a different package design, sealing parameters, and box size, did not have any failures after traveling over 11,000 ft via I-70." And Becton states that its tests did not reveal any defects in 60 mL syringes "that had been shipped to the Distribution Center in Plainfield, IN (at significantly less than 8,000 ft in elevation)," id. ¶ 34, but the record citation offered, Ex. 3 at BD000045-46, says nothing whatsoever about the altitude at which these syringes were shipped. As Rule 56(c)(1) explains, "[a] party asserting that a fact cannot be or is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record." We will thus present here only those factual claims that find support in the record.

[10] Becton incorrectly cites to Ex. 3 for this proposition, when it is actually contained in Ex. 4 at BD000057.

Cuautitlan varied between 5.0% and 16%, which exceeded the Acceptable Quality Limit of 0.25%. Def.'s Facts ¶ 27 (citing Ex. 3 at BD000044); Pls.' Resp. to Facts ¶ 27. Becton then initiated an investigation, id. ¶ 29 (citing Ex. 4 at BD000057), that revealed that no additional complaints had been recorded in 2007, id. ¶ 30 (citing Ex. 4 at BD000057; Ex. 5 at BD000069),[11] and showed that the affected 60 mL syringes were manufactured on 860 Line 2 in Columbus, Nebraska. Def.'s Facts ¶ 31 (citing Ex. 4 at BD000057; Ex. 5 at BD000069). The normal route for lots shipped to Mexico was by truck from Swedesboro, New Jersey, on a route which passes over elevations upwards of 8,000 feet. Def.'s Facts ¶ 36 (citing Ex. 3 at BD000046).[12] Visual inspections of lots

[11] Plaintiffs observe that "Exhibit 69 states that 'A review of the complaint history noted no packaging complaints for lots manufactured in 2007 for this particular catalog number,' it does not state that 'no other complaints had been recorded in 2007 regarding open seals,'" Pls.' Resp. to Facts ¶ 30 -- ignoring the fact that BD000057 contains the latter statement. This is not the only place where plaintiffs deny a Becton factual claim apparently due to a failure to read the record carefully. We will ignore such unjustified denials.

[12] Plaintiffs assert that they "lack[] information, knowledge, or belief regarding what defendant's normal transportation routes are, and or the mechanism or vehicle by which the transportation took place," Pls.' Resp. to Facts ¶ 36, thus ignoring the record evidence describing precisely the "normal transportation route" and the mechanism -- truck -- by which the syringes are transported. Ex. 3 at BD000046. Where (continued...)

from Mexico and from the distribution center in Plainfield, Indiana, revealed an open seal rate of 3.13% to 4.69% in the lots from Mexico and of 0.00% to 0.31% in the lots from Plainfield. Ex. 3 at BD000046. Becton's investigation thus focused on the effects of altitude on the syringes. Id. ¶ 35 (citing Ex. 3 at BD000046).

Becton produced experimental packages on 860 Line 2 in Columbus and subjected them to real-world conditions in high-altitude areas and in an altitude chamber at its headquarters. Id. ¶ 37; Pls.' Resp. to Facts ¶ 37. This testing produced no open seals under real-world conditions, but did show "seal creep that could potentially lead to an open package." Def.'s Facts ¶ 38 (quoting Ex. 3 at BD000047); Pls.' Resp. to Facts ¶ 38. Becton also compared package integrity between two groups of 60 mL syringes manufactured on 860 Line 2 -- one manufactured in July of 2007, the other in November of 2007. Def.'s Facts ¶ 39; Pls.' Resp. to Facts ¶ 39. On November 28, 2007, Becton conducted maintenance on 860 Line 2 which improved package

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[12](...continued)
plaintiffs have merely asserted that they "lack information, knowledge, or belief" as to factual statements that defendant has supported with a citation to the record, we have taken Becton's statement to be undisputed.

robustness. Def.'s Facts ¶ 40 (citing Ex. 3 at BD000052). The testing showed package failures in the July of 2007 product -- "[t]he real world product made in mid-July (7187506) had multiple open seals and package integrity following the real world testing. However, when altitude chamber testing was conducted, a very high level of open seals was found," Pls.' Resp. to Facts ¶ 41 (quoting Ex. 3 at BD000048); Def.'s Facts ¶ 40 -- with failure rates at 26%. Ex. 3 at BD000048. Real world testing revealed no open seals in the November, 2007 product, and altitude chamber testing produced only a one percent seal failure in this product. Def.'s Facts ¶ 41 (citing Ex. 3 at BD000048). The real-world testing took place at 8,000 and 11,000 feet, while the altitude chamber testing took place at 11,000 feet. Ex. 3 at BD000048.

Becton also attempted to "bracket the altitude at which seals were opening," Pls.' Resp. to Facts ¶ 42 (quoting Ex. 3 at BD000049), Def.'s Facts ¶ 42, by testing 60 mL syringes manufactured in July, 2007 along U.S. Interstate Highway 70 at various elevations. Def.'s Facts ¶ 43 (citing Ex. 3 at BD000049); Pls.' Resp. to Facts ¶ 43. "The results of the real-world testing did not clearly indicate at which altitude the packages could reach without opening." Pls.' Resp. to Facts ¶ 44

(quoting Ex. 3 at BD000049).[13] Becton likewise tested the "current production"[14] of 60 mL syringes at the Redlands, California distribution center, Def.'s Facts ¶ 45 (citing Ex. 3 at BD000049), which demonstrated some package failures in products that crossed I-70 (at 11,000 feet), but not in products that crossed I-80 (at 8,000 feet). Id. ¶ 47.

At the conclusion of Becton's investigation, a Field Action Committee convened to "discuss how to handle 60 ml LL product in the market" and recommended a recall. Ex. 4 at BD000061; Def.'s Facts ¶ 48-50. By a July 15, 2008 letter, Becton then sent out notice of the recall. Def.'s Facts ¶ 51 (citing Ex. 2); Pls.' Facts ¶ 51.

Becton has produced bills of lading and delivery note/packing lists, dated January 7, 2008, showing that a carrier, Werner Enterprises, transported Becton products from

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[13] Defendant suggests that "AQL was not exceeded at altitudes below 7,000 feet. " Def.'s Facts ¶ 44. Given that the Acceptable Quality Limit is 0.25%, Def.'s Facts ¶ 27 (citing Ex. 3 at BD000044), and that Ex. 3 at BD000049 reveals 0.31% open seals in one lot at 6,000 feet, this statement appears to be incorrect.

[14] Becton alleges that the tested packages "were manufactured in Columbus, NE in June of 2008." Def.'s Facts ¶ 45. While this allegation finds no support in the cited record, the uncontradicted record does state that its investigation was "of current production." Ex. 3 at BD000049.

Columbus, Nebraska to Swedesboro, New Jersey, Def.'s Facts ¶ 62-63 (citing Exs. 8-9).[15] The delivery note/packing lists reference a product described as "Syringe 60 mL LL Latex Free," with a product number of "309653" -- the same product number identified on Becton's recall notice -- and show that the shipments were transported by "Truck - FTL" to Swedesboro, NJ. Id. ¶¶ 63-65 (citing Exs. 2 and 9).[16] Becton supplies another bill of lading and delivery note/packing list, dated January 21, 2008, showing that the carrier A Duie Pyle transported "Syringe 60 mL LL Latex Free Configur," with the product number "309653," from Swedesboro, New Jersey to Delaware Valley Surgical Company at Boothwyn, Pennsylvania by "Truck LTL." Ex. 10 at BD000011, BD000018; Def.'s Facts ¶ 66. Dr. Noone testified that he bought

[15] Plaintiffs assert that they "lack[] information, knowledge, or belief regarding what defendant's documentation demonstrates," Pls.' Resp. to Facts ¶¶ 62-63, which we take to challenge defendant's assertion that the delivery note/packing lists describe the same shipment as the bills of lading. Because the shipment numbers printed on the delivery note/packing lists correspond to those on the bills of lading, we conclude that this assertion is supported by Becton's record citation.

[16] Plaintiffs "note[] that defendant admits that some of its syringes are transported via cargo aircraft," Pls.' Resp. to Facts ¶ 36, citing "BD000063." This exhibit has not been introduced by either party, and we will thus not consider plaintiffs' allegation in ruling on Becton's motion.

his syringes through "Delaware Valley Surgical Supply." Id. ¶ 67 (citing Dep. of Dr. Noone at 179).

Finally, Becton notes that no points in Nebraska or east of Nebraska in the continental United States exceed altitudes of 7,000 feet. Def.'s Facts ¶ 68 (citing United States Geological Survey, Ex. 7 at 3-5).

II. Analysis

On a motion for summary judgment, it is well-rehearsed that "[t]he moving party bears the initial burden of showing that the non-movant has failed to establish one or more essential elements of its case." Connection Training Servs. v. City of Phila., 358 Fed. Appx. 315, 318 (3d Cir. 2009) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). If the moving party meets its burden, "the non-movant must go beyond the pleadings and come forward with specific facts indicating a genuine issue for trial." Id. (citing Celotex, 477 U.S. at 324). A factual dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. . . . The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the

plaintiff." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 252 (1986) (cited in Sheddy Family Trust ex rel. Sheddy v. Piatt Twp., 404 Fed. Appx. 629, 631 (3d Cir. 2010)). Of course, we "must draw all reasonable inferences in favor of the nonmoving party, and [we] may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000) (cited in Eisenberry v. Shaw Bros., 2011 WL 1226881, at *1 (3d Cir. 2011)).

A. Defectiveness as an Element of Plaintiffs' Claims

As we have already noted, plaintiffs assert claims for (1) negligence, (2) strict liability under § 402A of the Restatement (Second) of Torts, (3) breach of express and implied warranty of merchantability, (4) breach of express and implied warranty of fitness for a particular purpose, and (5) loss of consortium (on Donald's behalf only). Becton argues that "[u]nder theories of negligence, strict liability and warranty, the plaintiff must prove, as a threshold matter, that the product at issue was defective." Def.'s MSJ at 4.

On the one hand, interpreting Delaware law, our Court of Appeals has approved the proposition that as to "negligent design/manufacturing, strict liability, and implied warranty of

merchantability claims . . . 'the plaintiff must establish that the product was defective' in order to prevail." Baylis v. Red Lion Group, Inc., 214 Fed. Appx. 193, 195 (3d Cir. 2007). But as Judge Robreno has explained, with reference to Pennsylvania law, "although it may be clouded by the frequent muddying of the strict liability waters with concepts of negligence, a products liability action based on negligence does not require proof of a defect." Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 753 n.13 (E.D. Pa. 2007). Judge Robreno cites Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003) (internal citations and quotation marks omitted), in which the Pennsylvania Supreme Court rejected appellants' argument that if

> the trial court properly granted summary judgment on Appellee's strict liability claim, then perforce we must hold that her negligence claim also fails. This reasoning is deeply flawed and we decline to adopt it. As we discussed supra, negligence and strict liability are distinct legal theories. Strict liability examines the product itself, and sternly eschews considerations of the reasonableness of the conduct of the manufacturer. In contrast, a negligence cause of action revolves around an examination of the conduct of the defendant. . . . It is axiomatic that in order to maintain a negligence action, the plaintiff must show that the defendant had a duty to conform to a certain standard of conduct; that the defendant breached that duty; that

such breach caused the injury in question; and actual loss or damage.

We will therefore reject Becton's attempt to defeat plaintiffs' negligence claim by asserting the absence of a genuine dispute as to whether defendant's product was defective.

Plaintiffs' remaining claims,[17] on the other hand, all do involve as a requisite element a showing of product defect, though the meaning of "defect" varies depending on the claim. To prevail in a products liability case, "the plaintiff must prove that (1) the product is defective, (2) the defect existed when it left the defendant's hands, and (3) the defect caused the plaintiff's injury," Hadar v. AVCO Corp., 886 A.2d 225, 228 (Pa. Super. 2005), where "'a product is defective if it is unsafe for its intended use.'" Id. (quoting Burch v. Sears, Roebuck & Co., 467 A.2d 615, 618 (Pa. Super. 1983)). Judge Baylson has observed that the "cause of action for implied warranty of merchantability requires essentially the same elements as [a] strict liability action." Saccomandi v. Delta Airlines, Inc., 2008 WL 3919365, at *4 (E.D. Pa. 2008); see also Gumbs v. Int'l Harvester, Inc., 718 F.2d 88, 94 n.10 (3d Cir. 1983) ("Both theories require that the

[17] Excluding Donald's loss of consortium claim, which we will consider separately in Section II.D.

product in question be defective at the time it leaves the hands of the seller."). However, the defects which may give rise to an implied warranty of merchantability action are enumerated by negative implication in 18 Pa. Cons. Stat. Ann. § 2314.[18] Finally, "a warranty of fitness for a particular purpose requires that the seller had reason to know of the buyer's particular purpose at the time of contracting, that the buyer was relying on the seller's expertise, and that the goods purchased were defective," Thomas v. Hamilton Beach/Proctor-Silex, Inc., 2007 WL 2080485, at *3 n.5 (W.D. Pa. 2007), where defectiveness turns on whether the goods are "fit for such purpose." § 2315.

In analyzing Becton's arguments as to whether there is a genuine dispute regarding the defectiveness of its product, then, we will keep in mind that this point only concerns plaintiffs' strict liability and warranty claims.

[18] Under § 2314, merchantable goods must (1) pass without objection in the trade; (2) be of fair average quality; (3) be fit for ordinary purposes; (4) run of even kind, quality, and quantity; (5) be adequately contained, packaged, and labeled; and (6) conform to promises on the container or label.

B. Plaintiffs' Strict Liability and Warranty Claims

1. Admissibility of Defendant's Recall and Investigation and Dr. Noone's Opinion

Becton argues that "[p]laintiffs are unable to meet their burden of proof in establishing a defect in any product manufactured or sold by BD that was used to treat Mrs. Pusey" because "[t]he sole basis for Plaintiffs' claims -- the recall of the 60 mL syringe -- is neither admissible as a matter of law nor probative as a matter of fact." Def.'s MSJ at 5. Plaintiffs respond that "defendant's recall of its product is not a Subsequent Remedial Measure," since "[t]he recall of the defendant's product took place prior to the recognition of plaintiff's injury." Pls.' Resp. at 7 (emphasis in original).

Both parties cite to Fed. R. Evid. 407, providing that

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

As our Court of Appeals has clarified, Rule 407 excludes "evidence of a remedial measure taken after the occurrence of harm caused by an event," Sell v. Ingersoll-Rand Co., 136 Fed. Appx. 545, 546 (3d Cir. 2005), so that the critical juncture for determining admissibility under Rule 407 is the occurrence of harm, not the event precipitating that harm.

Despite their quotation of Rule 407, plaintiffs suggest that the Rule's operation turns not on the occurrence of harm -- and not even on the event from which that harm arises -- but on the "recognition" of harm. This is a transparent attempt to stretch Rule 407 to cover the facts of this case since "[t]he recall letter is dated July 15, 2008, [and] Dr. Noone became aware of Mrs. Pusey's infection on July 17, 2008." Pls.' Resp. at 7. But the Rule is not ductile enough to withstand plaintiffs' manipulations. Plaintiffs' complaint asserts that Judith developed an infection within forty-eight hours of the procedure performed on July 11, 2008, Pls.' Compl. ¶ 11; Def.'s Facts ¶ 5; Pls.' Resp. to Facts ¶ 5, a claim Dr. Noone corroborated. Dep. of Dr. Noone at 177. Because Becton's recall notice of July 15, 2008 followed the occurrence of harm to Judith, evidence of the recall is inadmissible under Rule 407.

An expert may base an opinion or inference upon facts or data "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" even if the facts and data are not admissible in evidence, Fed. R. Evid. 703, so that an expert may offer an opinion based upon a subsequent remedial measure. See Pineda v. Ford Motor Co., 520 F.3d 237, 247 (3d Cir. 2008) (permitting engineer to rely upon subsequently issued warnings and alternative safety instructions in forming opinion that earlier service manual failed to provide adequate instructions and warnings).

But plaintiffs have not qualified Dr. Noone as an expert in this case. Lay testimony "is limited to those opinions or inferences which are . . . rationally based on the perception of the witness," Fed. R. Evid. 701, which is to say that the witness must "have firsthand knowledge of the factual predicates that form the basis for the opinion." Gov't of Virgin Islands v. Knight, 989 F.2d 619, 629 (3d Cir. 1993). Because Dr. Noone testified that his opinion as to the role of defendant's syringe in causing Judith's infection was based entirely on the recall notice he received from defendant, Dep. of Dr. Noone at 192, and because Dr. Noone had no first-hand knowledge of this recall, Dr.

Noone's opinion regarding the contribution of Becton's syringe to Judith's injury constitutes inadmissible lay testimony.

Since "[o]nly evidence admissible at trial may be used to test a summary judgment motion," Williams v. Borough of West Chester, 891 F.2d 458, 471 (3d Cir. 1989), we cannot consider either Becton's recall of the 60 mL syringes or Dr. Noone's opinion that it was defendant's syringe that caused Judith's infection. Nonetheless, Becton sweeps overbroad when it asserts that "[t]he sole basis for Plaintiffs' claims -- the recall of the 60 mL syringe -- is [not] admissible as a matter of law," Def.'s MSJ at 5, for there is other evidence in the record that may support plaintiffs' claim of a product defect: Becton's own investigation of its 60 mL syringes.

Our Court of Appeals has not squarely ruled on the question of whether post-injury investigations qualify as subsequent remedial measures.[19] We need not tarry long on this

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[19] On the one hand, our Court of Appeals observed in Complaint of Consolidation Coal Co., 123 F.3d 126, 136 (3d Cir. 1997), that "there is authority supporting the exclusion of evidence of post-accident investigations under Rule 407." On the other hand, in Consolidation Coal the Court excluded a report that both contained a discussion of a post-accident investigation and implemented subsequent remedial measures. Moreover, the Tenth Circuit held in Rocky Mountain Helicopters, Inc. v. Bell Helicopters Textron, 805 F.2d 907, 918 (10th Cir. 1986), that (continued...)

point, however, because it is evident that Becton's investigation of its syringes preceded Judith's injury, and hence is not "subsequent" under Rule 407. See Def.'s Facts ¶ 48 (noting that "at the conclusion of the investigation," Becton convened a Field Action Committee "to recommend corrective action"); Ex. 5 at BD000064 (stating that Field Action Committee met on June 11, 2008); Def.'s Facts ¶¶ 76, 80 (notably, Judith developed "symptoms of swelling and redness" between July 11 and July 17, 2008). Evidence regarding Becton's investigation is thus admissible under Rule 407.

2. Proving Defect in the Syringe Used on Judith

In their complaint, plaintiffs allege that Becton's syringe was defective in eight ways, which actually amount to three types of defects: (1) "[d]efendant, BD, failed to adequately package its product," Pls.' Compl. ¶ 26(e), (f); (2) "[t]he package seal and package seal integrity (and resulting

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[19](...continued)
"[i]t would strain the spirit of the remedial measure prohibition in Rule 407 to extend its shield to evidence contained in post-event tests or reports." In his dissent in Consolidation Coal, Judge McKee cited Rocky Mountain Helicopters to suggest that evidence of remedial measures might be redacted from reports that also discuss post-accident investigations, which he argued should otherwise be admissible. 123 F.3d at 138 n.3.

product sterility) was [sic] adversely affected when the product was exposed to low atmospheric pressure during shipment of the product," id. 26(a); and (3) Becton failed to take precautions in light of the above defects, id. ¶ 26(b), (c), such as warning users. Id. ¶ 26(d), (g).

Becton first argues that evidence of a recall (and presumably of an investigation showing the presence of defects among products) cannot prove that a particular product is defective. Def.'s MSJ at 6-7. To support this proposition, Becton cites Vockie v. General Motors Corp., 66 F.R.D. 57, 61 (E.D. Pa. 1975), which explained that "the fact of a defect in a particular [product is] required to be proved by direct evidence," and that evidence of a recall "has minimal probative value to the existence of a defect in a particular vehicle."

We first note that Becton's quotation from Vockie does not accurately summarize Pennsylvania law on defectiveness. A plaintiff can show a product was defective "by pointing to some specific dereliction by the manufacturer in constructing or designing the product," Ocean Barge Trans. Co. v. Hess Oil V.I. Corp., 726 F.2d 121, 124 (3d Cir. 1984), but it is also true that "under Pennsylvania law a product may be found defective if it 'functioned improperly in the absence of abnormal use and

reasonable secondary causes.'" Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992) (quoting Greco v. Bucciconi Eng'g, 407 F.2d 87, 89-90 (3d Cir. 1969)).

And since a plaintiff can only prove defectiveness by showing either a specific defect or a malfunction, see, e.g., Breidor v. Sears, Roebuck and Co., 722 F.2d 1134, 1140 (3d Cir. 1983) (identifying specific defect and malfunction as methods of proving a "defective condition"), it is true that a plaintiff must have some evidence regarding the particular product's defect or malfunction to demonstrate defectiveness. As the Pennsylvania Superior Court explained in Dansak v. Cameron Coca-Cola Bottling Co., Inc., 703 A.2d 489, 496 (Pa. Super. 1997) (citations and quotation marks omitted),

> Although proof of a specific defect is not essential to establish liability under [the malfunction] theory, the plaintiff cannot depend upon conjecture or guesswork. The mere fact that an accident happens, even in this enlightened age, does not take the injured plaintiff to the jury. The malfunction theory, thus, does not relieve the burden of establishing a defect. However, the malfunction itself is circumstantial evidence of a defective condition.

We will consider the import of this case law further after examining Becton's account of what its investigation revealed.

Becton asserts that evidence from its investigation "contradicts Plaintiffs' assertion that a specific product used to treat Mrs. Pusey was defective," Def.'s MSJ at 13, since

> BD recalled its 60 mL syringes after a detailed engineering investigation demonstrated that package seal integrity was not affected unless syringes were transported at altitudes exceeding at least 7,000 feet, and more likely 8,000 feet. Even at such altitudes, BD's testing produced package failure at a rate of less than 1%. Any syringe used to treat Mrs. Pusey would have been manufactured in Columbus, Nebraska, and shipped by truck to BD's Distribution Center in Swedesboro, New Jersey, before being picked up and delivered to Dr. Noone's practice in Bryn Mawr, Pennsylvania. Maximum altitudes on any conceivable transportation route between Columbus and Bryn Mawr would not even approach the levels that gave rise to the recall.

Id. (internal citations omitted).

But this is not what Becton's investigation of its 60 mL syringes showed. As we have already noted, Becton's testing revealed that even below 7,000 feet, it observed open seals with a frequency that exceeded its Acceptable Quality Limit, if only slightly. See supra Part I, n.14. Moreover, while Becton's testing revealed real-world failure rates at 8,000 and 11,000 feet that were less than one percent, its altitude chamber testing at 11,000 feet produced a failure rate of 26%. Ex. 3 at

BD000048. And the product lots that initially triggered Becton's investigation and later recall -- those examined in Cuautitlan, Mexico in June of 2007 -- demonstrated seal failure rates up to 16%. Ex. 3 at BD000044.

As for the question of shipping, Becton asks that we conclude from a few bills of lading and packing lists that any syringe used on Judith must have been transported by truck at elevations of less than 7,000 feet. Def.'s MSJ at 13 (citing Def.'s Facts ¶¶ 61-67). But Becton does not even claim that these bills and lists describe shipments that included the particular syringe used on Judith; it merely asserts that these are "representative shipping documents." Def.'s Facts ¶ 61. Moreover, Becton seems to ask us to draw the inference that any shipment trucked from Nebraska to Pennsylvania must necessarily travel directly and only traverse points east of its starting point. See Def.'s MSJ at 13. It has provided us with no information that would allow us to reach this conclusion, however, and we will not draw such an inference unaided.[20]

[20] To illustrate our reasons for declining to draw such an inference, we note that defendant admits that the normal route for lots shipped to Cuautitlan was from Columbus, Nebraska, to Swedesboro, New Jersey, to Laredo, Texas, to Mexico City. Def.'s Facts ¶ 36. A casual glance at any map reveals that this is not (continued...)

Given that we "must draw all reasonable inferences in favor of the nonmoving party, and [we] may not make credibility determinations or weigh the evidence," Reeves, 530 U.S. at 150 (2000), we would thus summarize the results of Becton's investigations quite differently. Though Becton asserts that it "was able to isolate the conditions that gave rise to the small number of package failures," Def.'s MSJ at 13, we believe that the results of its investigations were in fact more equivocal. These investigations revealed real-world seal failure rates up to 16% and altitude chamber failure rates up to 26% under certain conditions, but did not conclusively identify under what circumstances the syringes would not be subject to seal failure. See Pls.' Resp. at 13 ("Defendant's testing of its product did not indicate at what altitude the packages could reach without opening.") We will not encroach upon the role of the jury by interpreting evidence from the investigations to draw any conclusions more ambitious than these. As for the syringe used on Judith, we will not accept defendant's invitation to speculate on the route it took from Nebraska to Pennsylvania.

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[20](...continued)
the most direct route from Columbus to Cuautitlan. We can have little confidence, consequently, that trucking routes always trace a straight line between source and destination.

But even upon this account of the facts, and even though plaintiffs may prove that the syringe used on Judith was defective by either direct or indirect evidence, plaintiffs still have not adduced facts supported by the record that indicate a genuine dispute exists as to whether this particular product was defective. It bears repeating here that neither Dr. Noone nor any member of his staff observed a package seal failure in any 60 mL syringe used to treat Judith. See pp. 9-10 above. At worst, the evidence shows that up to 26% of Becton's syringes were defective in the sense that they were inadequately packaged, resulting in compromised package seal integrity under certain altitude conditions, and hence possibly containing latent dangers about which Becton should have warned users[21] -- the three types of defects alleged in plaintiffs' complaint. Pls.' Compl. ¶ 26. Such evidence still does not show that the particular syringe used on Judith was itself defective in these ways or was even in the class of syringes subjected to high altitude transport -- as plaintiffs must show if proving defect by direct evidence -- or

[21] Under Pennsylvania law, "a product may be found to be defective and unreasonably dangerous if its manufacturer fails to warn the user or consumer of latent dangers in the product's use or operation." Petree v. Victor Fluid Power, Inc., 831 F.2d 1191, 1194 (3d Cir. 1987).

that it malfunctioned, as the indirect approach to demonstrating defect requires.

Benton has it right when it states that "Plaintiffs have no evidence whatsoever to suggest, much less prove, a defect in any BD product used to treat Plaintiff Judith Pusey." Def.'s MSJ at 10. Instead, plaintiffs merely rely on "conjecture or guesswork," Dansak, 703 A.2d at 496, when they hypothesize that the possibility of seal failure among products of the same model under certain circumstances -- which may or may not have existed here -- means that the particular syringe used on Judith was also subject to such failure. Because plaintiffs cannot point to any admissible evidence suggesting a defect in the syringe used on Judith,[22] and because plaintiffs must show this syringe was defective in order to succeed on their strict liability or warranty claims -- which they most assuredly have not done[23] --

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[22] If the syringe used on Judith was not inadequately packaged, and this packaging was not compromised, this syringe consequently did not contain latent dangers and failure to warn about such dangers therefore did not constitute a defect.

[23] Had Becton's investigation shown failure rates significantly higher than the 1% to 26% range, we might have crossed the threshold from speculation to a reasonable inference. But on this record -- where there is no evidence of defect as to Judith's syringe or even as to the class of shipments from which her syringe was drawn -- a jury could only guess at a longshot,

(continued...)

we must grant Benton's motion for summary judgment as to the Puseys' claims for strict products liability, breach of warranty of merchantability, and breach of warranty of fitness.

C. Plaintiff's Negligence Claim

We are thus left only with plaintiffs' negligence claim. As we have already explained, to maintain a negligence action a plaintiff in Pennsylvania must show that the defendant had a duty to conform to a certain standard of conduct, that it breached that duty, that such breach caused an injury, and that it resulted in actual loss or damage. Phillips, 841 A.2d at 1008.

Benton focuses on the causation requirement, arguing that "[t]here is no evidentiary basis to find a causal link between the recall and Mrs. Pusey's injuries," Def.'s MSJ at 16, and that "Plaintiffs cannot meet this burden simply by asserting that Mrs. Pusey developed an infection." Id. at 15. As Benton explains, id.,

> [T]o meet their burden of proving causation, Plaintiffs would need to demonstrate not only that a syringe used to treat Mrs. Pusey had been subjected to altitudes in excess of

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[23](...continued)
which it may not do.

> 7,000 or 8,000 feet, but that the altitude caused the package seal on the specific syringe to fail; that a coagulase negative staphylococcus organism entered both the package and the syringe; and that the infectious organism was transmitted from the syringe, through a needle, and into an implanted medical device, where it then crossed the barrier of the device and was released into Mrs. Pusey's chest.

Benton also notes that "plaintiff[s] made no attempt to refute any of the[] alternative potential causes," such as "the saline solution and needles used in the procedure." Id. at 16. Plaintiffs respond that "[b]ased upon all of the facts, however, it was Dr. Noone's opinion that the infection was a function of defendant's contaminated syringe." Pls.' Resp. at 14.

We have already explained that because Dr. Noone was not qualified as an expert in this matter, and because his opinion as to the role of Becton's syringe in causing Judith's infection was based entirely on a recall of which he had no personal knowledge, we cannot consider his opinion in ruling on Becton's motion for summary judgment. See supra Part II.B.1. Plaintiffs have pointed to no evidence in the record, other than Dr. Noone's inadmissible opinion, suggesting that Benton's syringe caused Judith's injury or excluding the contribution of other possible causes. Consequently, there is no genuine issue

of fact as to whether the syringe caused this injury, and we will grant summary judgment as to plaintiffs' negligence claim.[24]

D. Donald's Consortium Claim

As Becton correctly notes, "an action for loss of consortium is a derivative action." Def.'s MSJ at 16. See, e.g., Scattaregia v. Shin Shen Wu, 495 A.2d 552, 554 (Pa. Super. 1985) ("[B]ecause a loss of consortium action has been viewed as derivative its success in this Commonwealth has always been dependent upon the injured spouse's right to recover."). Because we grant summary judgment with respect to plaintiffs' primary claims, we will also dismiss the claim for Donald's loss of consortium.

BY THE COURT:

__\s\Stewart Dalzell

[24] Since causation is also an element of plaintiffs' strict liability and warranty of merchantability claims, these claims would have foundered on plaintiffs' failure to show cause even if plaintiff could have pointed to evidence tending to establish defectiveness in the particular syringe used on Judith.